To: gay.dodson@pharmacy.texas.gov
Cc: Bauer, Eric
Subject: SBAR for TSHP on 291.133

Good afternoon Gay.
The information below is the follow-up from our conversation at TSHP in San Antonio last Sunday regarding 291.133.
I appreciate your willingness to consider our input.
The SBAR is a combination of input from Texas Health Fort Worth and Texas Health Dallas.
Thanks,
Eric

Situation:

The resource requirements for the record keeping aspects of 291.133 far exceed the benefits and should be reconsidered.

(2) Compounding records.

(A) Compounding pursuant to patient specific prescription drug orders. Compounding records for **all** compounded preparations shall be maintained by the pharmacy electronically or manually as part of the prescription drug or medication order, formula record, formula book, or compounding log and shall include:

(i) the date of preparation;

(ii) a complete formula, including methodology and necessary equipment which includes the brand name(s) of the raw materials, or if no brand name, the generic name(s) or official name and name(s) of the manufacturer(s) or distributor of the raw materials and the quantities of each;

(iii) signature or initials of the pharmacist or pharmacy technician or pharmacy technician trainee performing the compounding;

(iv) signature or initials of the pharmacist responsible for supervising pharmacy technicians or pharmacy technician trainees and conducting in-process and finals checks of compounded pharmaceuticals if pharmacy technicians or pharmacy technician trainees perform the compounding function;

(v) the quantity in units of finished preparation or amount of raw materials;

(vi) the container used and the number of units prepared; and

(vii) a reference to the location of the following documentation which may be maintained with other records, such as quality control records:

(I) the criteria used to determine the beyond-use date; and

(II) documentation of performance of quality control procedures.

Background:

- The rationale for the benefits of the new requirements primarily support more accurate tracking in the case of recalls or compounding errors.
- Prior to this law, documentation of the above elements in 100% of sterile compounded products was not common practice in hospital pharmacies.

- The negative aspects associated with the new requirements include the following:
    - Delayed patient care in acute situations
        - Epinephrine drip for an ICU patient who has destabilized
        - Initial antibiotics for a newly diagnosed septic patient
        - Thrombolytics for a stroke patient
    - Pulling pharmacists from clinical care for additional QA duties
    - Additional costs and complexity of commercial solutions
    - Adding more equipment (cameras, computers, and cabling) to cramped IV compounding rooms may negatively affect airflow quality and sterility

Assessment:

- Meeting the above requirement could be accomplished in several ways
    - Purchase and implementation of an I.T. solution, adding cost and complexity
    - Implementation of a manual process, potentially introducing particles and significant delay
    - Combination of some elements captured electronically while others captured manually
- Implementing the rules without modification would have a negative net impact on patient care in Texas
- The majority of the intended benefit could still be captured by risk stratifying the requirements for compounded products. This could be prescriptive by the TSBP, determined locally by a hospital's policy and procedures or some combination.

Recommendation:

- Modify the existing rule language to allow targeted record keeping for compounded products in Texas.
- The TSBP could define minimum acceptable standards for locally defined policies to include the following:
    - Batch-compounded sterile products
    - Compounded hazardous materials such as chemotherapy

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